K010887

JUN - 8 2001

Ohana Needle Company
64 Cheever Circle
Andover, MA 01810

510(k) Summary of Safety and Effectiveness

Submitter's Name: Ohana Needle company
64 Cheever Circle
Andover, MA 01810
(978) 470-0256
FAX: (978)975-7312
e-mail: SHODMD@AOL.com

Contact Person: Spencer H. Owades, DMD
(978) 685-7115

Date Prepared: March 21, 2001

Device Name:
Proprietary Name: Insulin Pen Needle Adapter
Common Name: Needle Adapter
Classification Name: Needle, Hypodermic, Single Lumen
Predicate Device **B-D 31g x 5/16 " pen needle (K 002938)**

Device Description

This device, a threaded needle hub adapter, will be used in conjunction with a pre-filled insulin pen syringe [K982842] and a standard, 30 gauge (11 mm long) insulin needle [K861150]. The adapter is made of medical-grade polycarbonate and has internal threads on the proximal end, which threads over the external threads of the distal end of the pen syringe. It also has external threads on the distal end, which fit inside the hub of the 30 gauge insulin needle. There is a 2-mm diameter lumen through the length of the adapter, which allows the extension of the insulin needle to pierce the rubber plug on the pen syringe. The lumen has a 60° chamfer that prevents the user from misguiding the needle into the metal cap of the pen syringe; the only way the needle can be secured to the adapter is by piercing the plug. The adapter has also been designed such that if the adapter is removed from the pen syringe while the needle is still in place, the user will not be subject to an inadvertent needle stick, as the extension is recessed inside the adapter.

The device is designed for multiple uses. It can be disinfected between uses by immersion in denatured alcohol.

Intended Use

This device is intended for use with a pen injector device for the subcutaneous injection of insulin.

As a combination device, it must be used as a completely assembled unit, i.e. with the adapter attached to the pen injector, and with the needle attached to the adapter.

Ohana Needle Company
64 Cheever Circle
Andover, MA 01810

Technological Characteristics

Comparison with predicate device

Element of Comparison	Subject Device	SE Device
Intended Use	Subcutaneous injection of insulin	Subcutaneous injection of insulin
Needle Diameter	30 gauge	31 Gauge
Needle Length	11 mm	8 mm
Needle Tip Configuration	Tri-beveled	Tri-beveled
Hub Material	Polypropylene	Polypropylene
Cover Color	White or purple	White
Usage	Adapter: re-usable Needle: single-use	Single-use
Dosage Accuracy*	±0.003 mg	±0.003 mg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2001

Mr. Spencer H. Owades
President
Ohana Needle Company
64 Cheever Circle
Andover, Massachusetts 01810-1727

Re: K010887
Trade/Device Name: Insulin Pen Needle Adapter
Regulation Number: 880. 5570
Regulatory Class: II
Product Code: FMI
Dated: March 22, 2001
Received: March 26, 2001

Dear Mr. Owades:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010887

Device Name: Insulin Pen Needle Adapter and Insulin Needle

Indications For Use:

Subcutaneous injection of insulin

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Paloma Ciccosta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010887